

EPA Jacket 88783-3

Vol.1 Part 1

PROCESSING REQUEST

Reg # 88783-3

Decision #500749

Description: New AI source R351

Electronic Label & Letter
(see PPLS):

OR

**Non Electronic
Label & Letter**
(Scanning required):

☐ Dated:

☐ Dated:

Only one label type should be selected

Other Materials Sent (see jacket):

☒ New CSF(s) Dated: Alt 1 1/22/15

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Deirdre Sunderland

Division: RD

Phone: 703.603.0851

Date: 10/29/15



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

October 6, 2015

Ann Tillman
Summit Agro USA, LLC
C/O Pyxis Regulatory Consulting Inc.
4110 136th Street, NW
Gig Harbor, WA 98332

Subject: PRIA CSF Amendment – Adding new unregistered source of active ingredient to
Alternate CSF #1
Product Name: Technical Sulfentrazone
EPA Registration Number: 88783-3
Application Date: February 26, 2015
Decision Number: 500749

Dear Ms. Tillman:

The Confidential Statement of Formula (CSF) referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

Please note that the record for this product currently contains the following CSFs:

- Basic CSF dated 7/12/2012
- Alternate CSF 1 dated 1/22/2015

Any CSFs other than those listed above are superseded/no longer valid. If you have any questions, please contact Deirdre Sunderland by phone at (703)603-0851, or via email at sunderland.deirdre@epa.gov.

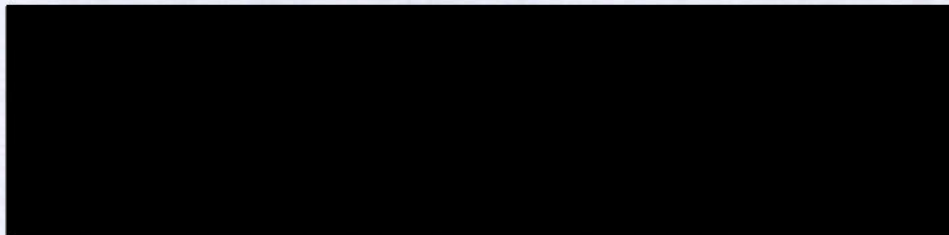
Sincerely,

A handwritten signature in dark ink, reading "Kathryn V. Montague", is written over a horizontal line.

Kathryn V. Montague, Product Manager 23
Herbicide Branch
Registration Division (7505P)
Office of Pesticide Programs

October 28, 2015

NOTE: Impurities in the proposed Alt CSF 1 (1/22/2015) containing the alternate source of AI were different from the basic. These new impurities were reviewed by Byron Backus of CITAB and determined to not be of toxicological concern. See note in CSF folder.



Manufacturing process information may be entitled to confidential treatment



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

FEE

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

DOCUMENT CONTAINS CONFIDENTIAL INFORMATION

DATE OUT: September / 14 / 2015

SUBJECT: **PRODUCT CHEMISTRY REVIEW OF MP [X] EP []**
DP BARCODE No.: DP428881 **EPA Reg. No.:** 88783-3a(a means Alt.#1)
PRODUCT NAME: Technical Sulfentrazone
COMPANY: Summit Agro USA, LLC
FOOD USE [Yes] INTEGRATED FORMULATION [X]
PCC: 129081 **Decision No.** 500749
ACTION CODE: R351 **Pesticidal use:** Herbicide

FROM: Hari Mukhoty, DVM, PhD
Product Chemistry Team
Technical Review Branch / RD (7505P)

shw. SBM 9/16/15

TO: Deirdre Sunderland, RMR / Kathryn Montague, RM 23
Herbicide Branch / RD (7505P)

INTRODUCTION:

The Registrant has submitted an amended basic CSF (dated: 01/22/2015) as alternate formulation (Alt. # 1) to the aforesaid basic for registration under EPA Reg. No. 88783-3. The product chemistry data have been submitted under MRIDs: 490590-01, -02, & 488907-01.

The aforesaid alternate MUP (Alt # 1) is manufactured by [REDACTED] The basic product is manufactured in [REDACTED]

Documents for Chemical Analyses were prepared by BIOAGRIC, Inc. 115 Obtuse Hill Road, Brookfield, CT 06804, USA.

Label text previously accepted indicates that this proposed MUP is intended to be formulated into end-use products with food uses & other non-food uses approved by EPA.

CITAB has been requested to evaluate the product chemistry data required for the registration of the proposed alternate MUP.

SUMMARY OF FINDINGS:

1. The proposed TGAI/MUP contains the active ingredient: Sulfentrazone (94.0%).
2. The overall mean of the active ingredient from the five batch analysis is 94.883% [MRID: 495590-02, Page 21].

DP BARCODE No.: 428881 **EPA Reg. No. :** 88783-3a **PRODUCT NAME:** Technical Sulfentrazone

3. The proposed nominal concentration of the active ingredient in the MUP is 94.0%. The nominal concentration of the active ingredient (94.0%) in alternate MUP matches with the label claim (94.0%). The certified limits of the active in this case is also identical to the proposed alternate technical product. The CLs of the active in the basic formulation needs to be corrected (reversed).

The nominal concentration of the active ingredient in the proposed alternate (94.0%) matches with that of the basic formulation (94.0%).

The certified limits of the active ingredient and impurities are standard [Proposed CSF dated 01/22/2015]. The impurity profile of the proposed Alt #1 formulation is different from that of the accepted basic formulation.

4. This CSF has been reviewed by I.I.A. group and they have concluded that it contains no inert ingredients to review.

5. The product chemistry data submitted for Group A corresponding to guidelines 830.1550 (product identity and composition), 830.1600 (description of materials used to produce the product), 830.1620 (description of production process), 830.1670 (discussion of formation of impurities), 830.1750 (certified limits) satisfy the product chemistry data requirements of 40 CFR §158.320, 158.325, 158.330, 158.340, and 158.350 respectively for the proposed formulation [MRIDs: 490590-01, -02 and 488907-01].

6. The active ingredient and the impurities were quantified and characterized by HPLC using UV detector set at 220 nm. [REDACTED] [MRID: 490590-02].

The method to determine active ingredient for precision, linearity and accuracy was validated [MRID: 490590-01 & -02].

Similar analytical techniques can also be applied for Enforcement Analytical Method.

7. There are no known impurities of toxicological concern in the technical Sulfentrazone. No nitroso compounds form [REDACTED]. No dioxin, PCBs or other impurities of toxicological significance arise using this process [MRID: 488907-01; Page 47].

CONCLUSIONS:

1. CITAB has reviewed the CSF (dated: 01/22/2015) for the proposed alternate TGA/MUP and has found it to be acceptable.

2. Product chemistry Group A data are satisfied and acceptable. Group B data are not required for the proposed alternate formulation.

DP BARCODE No.: 428881 **EPA Reg. No. :** 88783-3a **PRODUCT NAME:** Technical Sulfentrazone

PRODUCT CHEMISTRY DATA (SERIES 830 Group A)

Group A	Data Required Fulfilled	MRID No.
830.1550. Chemical Identity (same as in Product CSF dated 01/22/2015)	A	490590-01 & - 488907-01
830.1600. Beginning Materials	A	"
830.1620. Production process	A	"
830.1650. Formulation process	NA	
830.1670. Discussion of Impurities	A	"
830.1700. Preliminary Analysis #	A	"
830.1750. Certified Limits	A	CLs are standard.
830.1800. Enforcement Analytical Method #	A	490590-01, 488907-02 & - 03

A = Acceptable NA = Not Applicable G = data gap

Analytical Methods: The active ingredient and the impurities were quantified and characterized by HPLC using UV detector set at 220 nm. The water content was determined by Volumetric Karl Fischer Titration [MRID: 490590-02].

Sunderland, Deirdre

From: Montague, Kathryn V.
Sent: Tuesday, August 18, 2015 11:17 AM
To: Sunderland, Deirdre; Shah, Pv; Kenny, Daniel; Mathur, Shyam; Hashim, Masih
Subject: Citing old studies from canceled products to support new product, or new sources for existing products

Hello,

Last month, Deirdre received a review back, stating that a product (88783-3, a sulfentrazone technical product) could not cite existing MRIDs because they were originally submitted for a product which has since been canceled. We sent a 75-day letter out asking them to resubmit those studies and get new MRID #s. After push-back from the registrant (Ann Tillman of Pyxis, on behalf of Summit Agro), including a letter from OGC (Mark Dyer) stating that they can cite existing MRIDs from canceled products, I brought the issue to the PM workgroup for discussion. All agree that they can indeed cite the MRIDs from the canceled product, via selective citation on the data matrix. They can't cite the actual *product* as their "me-too", just the data. As long as we can verify that the composition of the product those original MRIDs supported is identical to the current product, and the studies are scientifically valid, there should not be an issue with using them.

Thank you,
Kay

Kathryn V. Montague
Product Manager 23
OPPTS/OPP/RD/HB
1200 Pennsylvania Ave., NW
Mailcode 7505P
Washington, DC 20460
Phone: (703)305-1243

Sunderland, Deirdre

From: Sunderland, Deirdre
Sent: Tuesday, August 04, 2015 8:57 AM
To: 'Ann Tillman'
Cc: Montague, Kathryn V.; Janelle Kay
Subject: RE: EPA Reg. No. 88783-3

Thanks for the information. I will look into it and get back to you.

From: Ann Tillman [mailto:Ann@PyxisRC.com]
Sent: Tuesday, August 04, 2015 8:45 AM
To: Sunderland, Deirdre
Cc: Montague, Kathryn V.; Janelle Kay
Subject: RE: EPA Reg. No. 88783-3

Deirdre,

It is our understanding that you may cite data for cancelled products per the Dyner letter, attached. If the Agency policy has changed, please send me documentation to that effect. Thanks.

Ann

*Ann M. Tillman, Ph.D.
Pyxis Regulatory Consulting, Inc.
4110 136th St. NW
Gig Harbor, WA 98332
Office (253) 853-7369
Fax (253) 853-5516
Email Ann@PyxisRC.com*

From: Sunderland, Deirdre [mailto:Sunderland.Deirdre@epa.gov]
Sent: July 31, 2015 6:25 AM
To: Ann Tillman <Ann@PyxisRC.com>
Cc: Montague, Kathryn V. <Montague.Kathryn@epa.gov>
Subject: EPA Reg. No. 88783-3

Good morning,

After reviewing your submission for EPA Reg. No. 88783-3 it has been determined that the MRID #s that were submitted (i.e., 49059001 and 49059002) are not acceptable because the product that they were originally submitted for has been cancelled. Please see the attached 75-day letter for more information.

Thanks,
Deirdre

Herbicide Branch
Registration Division
Office of Pesticide Programs
US Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington DC, 20460
703-603-0851



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
GENERAL COUNSEL

OCT 24 1996

VIA FACSIMILE

Leonard A. Miller, Esq.
Swidler & Berlin
3000 K Street, N.W. Suite 300
Washington, D.C. 20007-5116

Dear Mr. Miller:

This is in response to your request that the Environmental Protection Agency (EPA) confirm that an applicant for registration of a product containing the active ingredient metalaxyl may cite to data previously submitted by Ciba Crop Protection (Ciba) after the date of voluntary cancellation of Ciba's products containing metalaxyl.

As we have discussed by telephone, the voluntary cancellation of an original data submitter's registration does not preclude others from citing to the data submitted by the original data submitter. Neither, of course, does it preclude the data submitter from obtaining compensation for the use of such data. Further, as you are aware, the 10-year exclusive use period for data submitted by Ciba in support of its metalaxyl registrations has expired. For these reasons, any applicant seeking registration or amended registration may cite such data in support of registration without first obtaining the permission of Ciba, provided such applicant complies with the data compensation provisions of section 3(c)(1)(F).

I hope this adequately addresses your request. If you have any questions regarding this response, please call me at (202) 260-5085.

Sincerely,

A handwritten signature in dark ink, appearing to read "M. A. Dyner", is written over a horizontal line.

Mark A. Dyner
Pesticides and Toxic Substances
Division (2333)

cc: Connie Welch



Printed on Recycled Paper

Sunderland, Deirdre

From: Mike Kellogg <Mike@PyxisRC.com>
Sent: Friday, July 31, 2015 1:21 PM
To: Sunderland, Deirdre; Janelle Kay
Cc: Montague, Kathryn V.
Subject: RE: EPA Reg. No. 88783-3

Received.

Regards,
Mike Kellogg
Pyxis Regulatory Consulting, Inc.
4110 136th St. NW
Gig Harbor, WA 98332
T: 253-853-7369
F: 253-853-5516

From: Sunderland, Deirdre [mailto:Sunderland.Deirdre@epa.gov]
Sent: Friday, July 31, 2015 3:29 AM
To: Mike Kellogg; Janelle Kay
Cc: Montague, Kathryn V.
Subject: FW: EPA Reg. No. 88783-3

Good morning,

Per Ann's out of office email I am forwarding this on to avoid a time delay. Please confirm receipt.

Thanks,
Deirdre

From: Sunderland, Deirdre
Sent: Friday, July 31, 2015 6:25 AM
To: 'ann@pyxisRC.com'
Cc: Montague, Kathryn V.
Subject: EPA Reg. No. 88783-3

Good morning,

After reviewing your submission for EPA Reg. No. 88783-3 it has been determined that the MRID #s that were submitted (i.e., 49059001 and 49059002) are not acceptable because the product that they were originally submitted for has been cancelled. Please see the attached 75-day letter for more information.

Thanks,
Deirdre

Herbicide Branch
Registration Division
Office of Pesticide Programs
US Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington DC, 20460



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

July 29, 2015

OPP Decision Number: D-500749

Ann Tillman
Summit Agro USA, LLC
C/O Pyxis Regulatory Consulting Inc.
4110 136th Street, NW
Gig Harbor, WA 98332

Subject: Data Deficiency
Product Name: Technical Sulfentrazone
EPA File Symbol: 88783-3
Application Date: February 26, 2015
EPA Receipt Date: March 2, 2015

Dear Ms. Tillman:

The application referred to above has been determined, pursuant to 40 CFR §152.105, that it is incomplete or that further information is needed to complete the Agency's review. Therefore, the application is considered deficient. The item(s) specified below must be addressed before processing of the application can be completed. If such deficiencies cannot be corrected within 75 days from the date of this letter, you must notify the Agency within those 75 days of the date on which you expect to complete the application. If, after 75 days, you do not respond, or you subsequently fail to complete the application within the time scheduled for completion, the Agency will terminate any action on the application, and will treat the application as if it has been withdrawn by you. Any subsequent submission relating to the application must be submitted as a new application. As you see fit, you may also withdraw the registration application.

PRIA Due Date: November 23, 2015 75-days from today: October 14, 2015

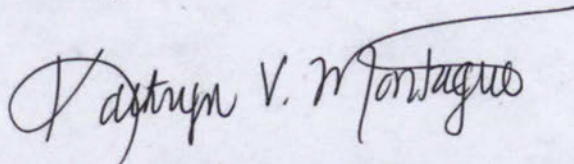
The deficiency identified in the Agency's review at this time is:

1. The studies that were cited (i.e., MRID 49059001 and 49059002) were submitted for a product that was cancelled and therefore, the MRIDs associated with these studies are no longer valid. These studies will need to be submitted in their entirety and be given new MRID numbers or new studies need to be submitted to address the five batch analyses data for the proposed production site.

Further review of your application and your response to the deficiencies may identify additional deficiencies and you will be so informed.

Please contact Deirdre Sunderland at (703)603-0851 or at sunderland.deirdre@epa.gov with a response and for any questions concerning this letter.

Sincerely,

A handwritten signature in dark ink, reading "Kathryn V. Montague". The signature is fluid and cursive, with a long horizontal line extending from the end of the name.

Kathryn V. Montague, Product Manager 23
Herbicide Branch
Registration Division (7505P)
Office of Pesticide Programs



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

FEE

DOCUMENT CONTAINS CONFIDENTIAL INFORMATION

DATE OUT: June / 24 / 2015

SUBJECT: **PRODUCT CHEMISTRY REVIEW OF MP [X] EP []**
DP BARCODE No.: DP427058 EPA Reg. No.: 88783-3
PRODUCT NAME: Technical Sulfentrazone
COMPANY: Summit Agro USA, LLC
FOOD USE [Yes] **INTEGRATED FORMULATION [X]**
PCC: 129081 Decision No. 500749
ACTION CODE: R351 Pesticidal use: Herbicide

FROM: Hari Mukhoty, DVM, PhD
Product Chemistry Team
Technical Review Branch / RD (7505P)

[Handwritten signatures and initials]
7-01-15

TO: Deirdre Sunderland, RMR / Kathryn Montague, RM 23
Herbicide Branch / RD (7505P)

INTRODUCTION:

The Registrant has submitted an amended CSF (dated: 01/22/2015) as alternate formulation (Alt. # 1) to the aforesaid basic for registration under EPA Reg. No. 88783-3. The product chemistry data have been cited from EPA Reg. No. 73801-3 supported by data from MRIDs: 490590-01 & -02.

The aforesaid alternate MUP is manufactured by [REDACTED]

Five batch Analyses for the alternate # 1 were not performed for the aforesaid product because the registrant cited data from another registered product EPA Reg. No. 73801-3.

Label text previously accepted indicates that this proposed MUP is intended to be formulated into end-use products with food uses & other terrestrial non-food crops approved by EPA.

CITAB has been requested to evaluate the product chemistry data required for the registration of the proposed alternate MUP.

SUMMARY OF FINDINGS:

1. The proposed alternate formulation (Alt. # 1/ amended to the basic of EPA Reg. No. 88783-3) is manufactured by [REDACTED]. The registrant did not submit data pertaining to the five batch analysis from this site under MRID: 495827-01.

2. The registrant cited product chemistry data from EPA Reg. No. 73801-3, another Sulfentrazone Technical formulation manufactured in another plant in [REDACTED]

Product ingredient source information may be entitled to confidential treatment

DP BARCODE No.: 427058 **EPA Reg. No. :** 88783-3 **PRODUCT NAME:** Technical Sulfentrazone

3. CITAB must require five batch analyses data from specific production site for registration of the proposed product. This is not the case in point.

CONCLUSIONS:

1. CITAB has reviewed the CSF (dated: 01/22/2015) for the proposed alternate TGAI/MUP and has found it to be unacceptable. This is because no five batch analyses data were submitted from the production site of the proposed alternate formulation.
2. The registrant should submit five batch analyses data from the manufacturing plant of the alternate technical product located in the [REDACTED] for registration of the proposed alternate technical formulation.

Product ingredient source information may be entitled to confidential treatment



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460
OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

DP BARCODE No.: D427058; FILE SYMBOL No.: 88783-3 (screen); PRODUCT NAME: Technical Sulfentrazone; DECISION No.: 500749; PC Code(s): 129081; ACTION CODE: R351; FOOD Use: Yes

DATE OUT: May 11, 2014

SUBJECT: Completeness check screening for technical product "Technical Sulfentrazone"

FROM: Shyam Mathur,
Product Chemistry Team Leader
CITAB / RD (7505P)

SBM 5/11/14

TO: Deirdre Sunderland / Kathryn Montague, RM 23
Herbicide Branch / RD (7505P)

Company Name: Summit Agro USA, LLC

Formulation Type: Herbicide

Active Ingredient(s): Sulfentrazone (94.0%)

MRID No(s): 490590-01 to -02 and 49582701

CONCLUSION:

Deficiencies: No

(if there are deficiencies they are indicated below each heading as Note 1, Note 2 Etc).

Group A: All required Data submitted

Note 1: 830.1670 (discussion of the formation of impurities) – there appears to be few new impurities identified in the alternate CSF #1 (dated 01-22-15; [REDACTED]) as compared to basic CSF (dated 02-15-2013; [REDACTED]). It is recommended that toxicity of these impurities be assessed by HED.

Group B: All required data cited

CSF: Alternate CSF #1 (Dated 01-22-2015; [REDACTED])
Basic CSF (dated 02-15-2013; [REDACTED])

Product Label: Not submitted.

Note to PM: If the deficiencies are found in the screen results, please inform the registrant and bring back to author of this report or to Joe the corrected deficiencies in response to 10 day letter, so that it can be attached to the original bean, if the data package is still in CITAB. New Bean is required in case the bean has been closed by CITAB. Thank you.

Product ingredient source information may be entitled to confidential treatment



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

March 6, 2015

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-500749
EPA File Symbol or Registration Number: 88783-3
Product Name: TECHNICAL SULFENTRAZONE
EPA Receipt Date: 02-Mar-2015
EPA Company Number: 88783
Company Name: SUMMIT AGRO USA, LLC

ANN M. TILLMAN
PYXIS REGULATORY CONSULTING, INC
SUMMIT AGRO USA, LLC
4110 136TH ST. NW
GIG HARBOR, WA 98332-

SUBJECT: Receipt of Registration Amendment Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your amendment and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R351

AMENDMENT;UNREGISTERED SOURCE OF ACTIVE INGREDIENT;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 347-8961.

Sincerely,

A handwritten signature in dark ink, appearing to be "m. j. h.", is written over the word "Sincerely,".

Front End Processing Staff
Information Technology & Resources Management Division

Receipt for Section 3

S: 965138

Milestone Email:

Regulatory Type: Product Registration - Section 3

Resubmission: ☐ Yes ☒ No

Application Type: Amendment

Fee For Service: ☐ Yes ☒ No

Company: 88783 SUMMIT AGRO USA, LLC

Billable: ☒ Yes ☐ No

V

Print Letter

Enter More Information

Tracking

Risk Manager: Registration Division, Risk Management Team 23

Product #: 88783-3

Product Name: TECHNICAL SULFENTRAZONE

Override#:

Me Too Section3:

Me Too Product Name:

Application Date: 26-Feb-2015

OPP Rec'd Date: 02-Mar-2015

Front End Date: 04-Mar-2015

Risk Manager Send Date:

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

Adding an unregistered source of active ingredient

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Receipt Content

Des

CSF

View/Edit

New Ingredient Request Date:

New Ingredient Received Date:

30

17

Fee for Service

{965138;~

This package includes the following

☐ New Registration

☒ Amendment

☒ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: _____

for Division

☐ AD

☐ BPPD

☒ RD

Risk Mgr. 23

Receipt No.

S- 965138

EPA File Symbol/Reg. No.

88783-3

Pin-Punch Date:

3/2/2015

☐ This item is NOT subject to FFS action.

Action Code:

Requested: R351

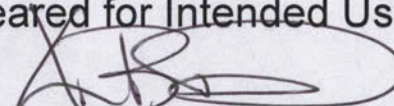
Granted: R351

Amount Due: \$ 12,556. ¹²

Parent/Child Decisions:

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: 

Date: 3-6-15

Remarks:

PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 3-2-15

Experts In-Processing Signature: B.B. Date 3-9-15 Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date

EPA Reg. Number: <u>88783-3</u>		EPA Receipt Date: <u>3-2-15</u>				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)			X		
	a) All <u>inerts</u> , including fragrances, approved for the proposed uses (see Footnote A) <u>N/A Tech. + Impur.</u>	yes	no			
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)					X
	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)			X		
5	a) Selective Method (Fee category experts use)	yes	no			
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of <u>Label</u> (Electronic labels on CD are encouraged and guidance is available)					X
7	Is the data package consistent with <u>PR Notice 86-5</u>			X		
8	<u>Notice of Filing</u> included with <u>petitions</u>					X

9	If applicable for conventional applications, <u>reduced risk rationale</u>			X
	<u>Required Data</u> and/or data waivers. See Footnote C.			
10	a) List study (or studies) not included with application			

Comments:

Documentation: Pass

Required forms are complete

Inerts: N/A

Technical & impurities only

11-B: Pass

MRID 495827

Status: Pass

KC 3/17/2015



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

March 11, 2015

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

PYXIS REGULATORY CONSULTING, INC
SUMMIT AGRO USA, LLC
4110 136TH ST. NW
GIG HARBOR, WA 98332

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 02-MAR-15. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

PYXIS REGULATORY CONSULTING, INC.

4110 136th St. NW
Gig Harbor, WA 98332

Phone: 253-853-7369
Fax: 253-853-5516
www.PyxisRC.com

CONTAINS CONFIDENTIAL BUSINESS INFORMATION

49582700

February 26, 2015

OVERNIGHT DELIVERY

Kathryn Montague (PM 23)
Document Processing Desk (REGFEE)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

RE: Summit Agro USA, LLC
Sulfentrazone Technical (EPA Reg. No. 88783-3)
Application to Add Alternate Source of Active Ingredient
PRIA Category R351

On behalf of Summit Agro USA, LLC, we are submitting an application to amend the registration of Sulfentrazone Technical to add an alternate source of the active ingredient. In support of this application, we submit the following documents:

1. Application for a Pesticide Registration (EPA Form 8570-1)
2. Confidential Statement of Formula (EPA Form 8570-4) for Alternate #1 CSF
3. Certification with Respect to Citation of Data (EPA Form 8570-34)
4. Agency Internal Use Copy of the Data Matrix
5. Public File Copy of the Data Matrix
6. Copy of PRIA payment
7. A copy of this cover letter with Confidential Business Information redacted
8. Letter of Authorization from the owner of the data cited in support of this application
9. Letter of Authorization from Summit Agro USA, LLC
10. Product Specific Data (3 copies):

49582701

Volume 1	830.1750	Tillman, A. M. Technical Sulfentrazone: Certified Limits. <i>Contains Confidential Business Information.</i>
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This amendment does not require any changes to the product label.

Summit Agro USA, LLC has permission to cite data from the data owner and a letter of authorization is enclosed. The data that are cited were submitted to support Sulfentrazone Technical, EPA Reg. No. 73801-3. The product-specific data MRIDs are listed on the data matrices and in the table below and have been previously submitted, reviewed, and approved. Sulfentrazone Technical will be manufactured using the same process as described in the reports previously submitted by the manufacturer, [REDACTED]

Product ingredient source information may be entitled to confidential treatment

49059002

Please contact me ((253) 853-7369, Ann@PyxisRC.com) if you have any questions or need any additional information.

Ann M. Fuller

[illegible]

36



(a jhaver group company)

CIN: U24294TN1992PLC024115

Tagros Chemicals India Ltd.

"Jhaver Centre" Rajah Annamalai Building
IV Floor, 72, Marshalls Road
Egmore, Chennai-600 008, Tamilnadu, India.
Phone : +91 44 4200 7400 / 424 / 426
Fax : +91 44 2858 7873
E-mail : info@tagros.com
Web : www.tagros.com

Registration Division
Office of Pesticide Programs (7505 P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Attn: Kathryn Montague (PM 23)

Subject: Letter of Authorization
Permission to Cite Data

Dear Ms. Montague:

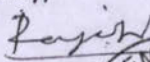
Tagros Chemicals India, Ltd. is informing the Agency that Summit Agro USA, LLC is authorized to cite the following data which is owned by Tagros Chemicals India, Ltd., in amending the registration of Summit Agro USA, LLC's product Sulfentrazone Technical:

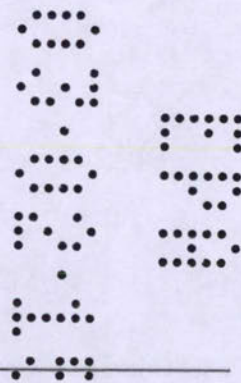
MRID	
49059001	49059002

This authorization is qualified to the extent that 1) neither the applicant nor any other person, except the Agency, shall have access to said data unless specifically authorized in writing by Tagros Chemicals India, Ltd.; 2) This authorization shall not be transferred by the applicant in any manner whatsoever without the express prior consent of Tagros Chemicals India, Ltd.

If you have any questions, please do not hesitate to contact me at +91 (44) 4200 7426.

Sincerely,


Rajesh Mathew
General Manager
Tagros Chemicals India, Ltd.



Works : A-4/1,2 & 3 Sipcot Industrial Complex, Pachayankuppam, Cuddalore - 607 005
Phone : +91-04142 - 239373, 239374, Fax : +91 - 04142 - 239375

Mumbai Off : No. 601, Express Chambers, V Floor, 72, Andheri - Kurla Road
Andheri (East), Mumbai - 400 069.
Phone : 022 - 4290 0800 (13 Lines) Telefax : 022-4290 0811



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Summit Agro USA, LLC c/o Pyxis Reg. Consulting 4110 136th St. NW Gig Harbor, WA 98332	EPA Registration Number/File Symbol 88783-3
Active Ingredient(s) and/or representative test compound(s) sulfentrazone	Date 2/26/15
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) TGA1	Product Name Technical Sulfentrazone

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature <i>Ann M. Tillman</i>	Date 2/26/15	Typed or Printed Name and Title Ann M. Tillman, Agent
------------------------------------	-----------------	--



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number Summit Agro USA, LLC/88783-3	2. EPA Product Manager K. Montague	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Summit Agro USA, LLC/Technical Sulfentrazone	PM# 23	
5. Name and Address of Applicant (Include ZIP Code) Summit Agro USA, LLC c/o Pyxis Regulatory Consulting Inc. 4110 136th St. NW Gig Harbor, WA 98332 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Amendment to add unregistered source of active ingredient. This application falls under PRIA Category R351 (57: Amendment adding new unregistered source). The fee has been paid (\$12,596) and the decision time line is 8 months.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input checked="" type="checkbox"/> Other (Specify) _____	PE lined fiberboard or metal drums
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 110, 55 lb		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Ann M. Tillman	Title Agent	Telephone No. (Include Area Code) (253) 853-7369
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Agent	
4. Typed Name Ann M. Tillman	5. Date 2/26/15	

Nicki Purnell

From: Ann Tillman
Sent: Wednesday, February 25, 2015 8:41 AM
To: Nicki Purnell
Subject: FW: Pay.gov Payment Confirmation: PRIA Service Fees

Categories: Task Help

For Summit Agro Technical Sulfentrazone amendment.

-----Original Message-----

From: notification@pay.gov [mailto:notification@pay.gov]
Sent: February 25, 2015 11:38 AM
To: Ann Tillman
Subject: Pay.gov Payment Confirmation: PRIA Service Fees

Your payment has been submitted to Pay.gov and the details are below. If you have any questions regarding this payment, please contact Michael Yanchulis at (703) 347-0237 or yanchulis.michael@epa.gov.

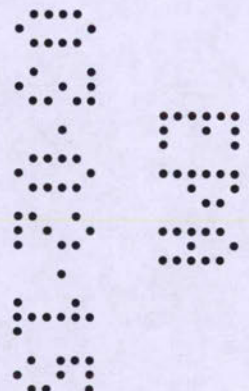
Application Name: PRIA Service Fees
Pay.gov Tracking ID: 25K009B4
Agency Tracking ID: 74759307851
Transaction Type: Sale
Transaction Date: 02/25/2015 11:37:29 AM EST

Account Holder Name: Susan Hill

Transaction Amount: \$12,596.00
Billing Address: 8000 Regency Pkwy
Billing Address 2: Suite 265
City: Cary
State/Province: North Carolina
Zip/Postal Code: 27518
Country: USA
Card Type: Visa
Card Number: *****4824

Registration Number: 88783-3
Company Name: Summit Agro USA, LLC
Company Number: 88783
Action Code: R351

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

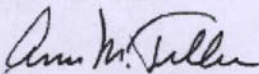


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DATA MATRIX

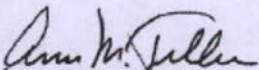
Date February 24, 2015			EPA Reg. No./File Symbol 88783-3		Page 1 of 25
Applicant's/Registrant's Name & Address Summit Agro USA, LLC 8000 Regency Park, Suite 265 Cary, NC 27518			Product Technical Sulfentrazone		
Ingredient Sulfentrazone (CAS No. 122836-35-5)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1550	Product Identity and Composition	49059001 ✓ 48890701	Tagros Chemicals India Ltd. Summit Agro USA, LLC	PER OWN	
830.1600	Description of Materials Used to Produce the Product	49059001 48890701	Tagros Chemicals India Ltd. Summit Agro USA, LLC	PER OWN	
830.1620	Description of Production Process	49059001 48890701	Tagros Chemicals India Ltd. Summit Agro USA, LLC	PER OWN	
830.1650	Description of Formulation Process				Not required ¹
830.1670	Discussion of Formation of Impurities	49059001 48890701	Tagros Chemicals India Ltd. Summit Agro USA, LLC	PER OWN	
830.1700	Preliminary Analysis	49059002 ✓ 48890702	Tagros Chemicals India Ltd. Summit Agro USA, LLC	PER OWN	
830.1750	Certified Limits	49059002 49059001 48890701	Tagros Chemicals India Ltd. Tagros Chemicals India Ltd. Summit Agro USA, LLC	PER PER OWN	
830.1800	Enforcement Analytical Method	49059002 48890702 48890703	Tagros Chemicals India Ltd. Summit Agro USA, LLC Summit Agro USA, LLC	PER OWN OWN	
Signature 			Name and Title Ann M. Tillman, Consultant		Date Feb. 24, 2015

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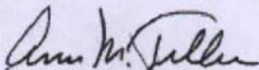
Date February 24, 2015			EPA Reg. No./File Symbol 88783-3		Page 2 of 25
Applicant's/Registrant's Name & Address Summit Agro USA, LLC 8000 Regency Park, Suite 265 Cary, NC 27518			Product Technical Sulfentrazone		
Ingredient Sulfentrazone (CAS No. 122836-35-5)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6302	Color	48890704	Summit Agro USA, LLC	OWN	
830.6303	Physical State	48890704	Summit Agro USA, LLC	OWN	
830.6304	Odor	48890704	Summit Agro USA, LLC	OWN	
830.6313	Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	48890704	Summit Agro USA, LLC	OWN	
830.6314	Oxidation/Reduction: Chemical Incompatibility	48890704	Summit Agro USA, LLC	OWN	
830.6315	Flammability	48890705	Summit Agro USA, LLC	OWN	Waiver ²
830.6316	Explosibility	48890705	Summit Agro USA, LLC	OWN	Waiver ³
830.6317	Storage Stability	49267701	Summit Agro USA, LLC	OWN	
830.6319	Miscibility				Not required ⁴
830.6320	Corrosion Characteristics	49267701	Summit Agro USA, LLC	OWN	
830.6321	Dielectric Breakdown Voltage				Not required ⁵
830.7000	pH	48890704	Summit Agro USA, LLC	OWN	
830.7050	UV/Visible Absorption	48890704	Summit Agro USA, LLC	OWN	
830.7100	Viscosity				Not required ⁶
830.7200	Melting Point/Melting Range	48890704	Summit Agro USA, LLC	OWN	
830.7220	Boiling Point/Boiling Range				Not required ⁷
Signature 			Name and Title Ann M. Tillman, Consultant		Date Feb. 24, 2015

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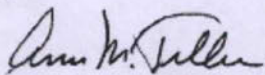
Date February 24, 2015			EPA Reg. No./File Symbol 88783-3		Page 3 of 25
Applicant's/Registrant's Name & Address Summit Agro USA, LLC 8000 Regency Park, Suite 265 Cary, NC 27518			Product Technical Sulfentrazone		
Ingredient Sulfentrazone (CAS No. 122836-35-5)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7300	Density/Relative Density/Bulk Density	48890704	Summit Agro USA, LLC	OWN	
830.7370	Dissociation Constants in Water	48890704	Summit Agro USA, LLC	OWN	
830.7520	Particle size, fiber length, diameter distribution	48890705	Summit Agro USA, LLC	OWN	Waiver ⁸
830.7550	Partition Coefficient (n-octanol/water), Shake Flask Method				See 830.7570
830.7560	Partition Coefficient (n-octanol/water), Generator Column Method				See 830.7570
830.7570	Partition Coefficient (n-octanol/water), Estimation by Liquid Chromatography	48890704	Summit Agro USA, LLC	OWN	
830.7840	Water Solubility: Column Elution Method; Shake Flask Method	48890704	Summit Agro USA, LLC	OWN	•••••
830.7860	Water Solubility, Generator Column Method				• See 830.7840
830.7950	Vapor Pressure	48890704	Summit Agro USA, LLC	PL	•••••
					•••••
870.1100 (81-1)	Acute Oral Toxicity: Rat	41911605 41911606		OLD OLD	••••• See endnote ⁹
870.1200 (81-2)	Acute Dermal Toxicity: Rat	41911607		OLD	••••• See endnote ¹⁰
Signature 			Name and Title Ann M. Tillman, Consultant		Date Feb. 24, 2015

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Applicant's/Registrant's Name & Address Summit Agro USA, LLC 8000 Regency Park, Suite 265 Cary, NC 27518		Product Technical Sulfentrazone			
Ingredient Sulfentrazone (CAS No. 122836-35-5)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.1300 (81-3)	Acute Inhalation Toxicity: Rat	42471002		OLD	See endnote ¹¹
870.2400 (81-4)	Primary Eye Irritation: Rabbit	41911608		OLD	See endnote ¹²
870.2500 (81-5)	Primary Dermal Irritation	41911609		OLD	See endnote ¹³
870.2600 (81-6)	Dermal Sensitization	41911610		OLD	See endnote ¹⁴
Generic Data Requirements					
850.2100	Acute Avian Oral Toxicity	41911617		OLD	See endnote ¹⁵
850.2200	Acute Avian Dietary Toxicity	41911618 41911619		OLD OLD	See endnote ¹⁶
850.2400	Wild Mammal Toxicity				Not required
850.2300	Avian Reproductive Toxicity	43355901 43355902		OLD OLD	See endnote ¹⁷
850.2500	Simulated or Actual Field Testing				Not required
850.1075	Freshwater Fish Toxicity	41911620 41911621		OLD OLD	See endnote ¹⁸
850.1010	Freshwater Invertebrate Toxicity	41911622		OLD	See endnote ¹⁹
Signature 			Name and Title Ann M. Tillman, Consultant		Date Feb. 24, 2015

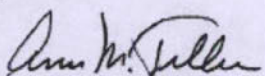
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Ingredient Sulfentrazone (CAS No. 122836-35-5)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.1025, 850.1035, 850.1045, 850.1055, 850.1075	Acute Toxicity Estuarine and Marine Organisms	43588602 44054901 43588603		OLD OLD OLD	See endnote ²⁰
850.1300	Aquatic Invertebrate Life Cycle (Freshwater)	43588605		OLD	See endnote ²¹
850.1350	Aquatic Invertebrate Life Cycle (Saltwater)				Not required
850.1400	Fish Early Life Stage (Freshwater)	43588604		OLD	See endnote ²²
850.1400	Fish Early Life Stage (Saltwater)				Not required
850.1500	Life Cycle Fish				Not required
850.1710, 850.1730, 850.1850	Aquatic Organisms Bioavailability, Biomagnification, Toxicity	43345433		OLD	Not required ²³
850.1950	Simulated or Actual Field Testing for Aquatic Organisms				Not required
850.1735	Whole Sediment: Acute Freshwater Invertebrates				Not required
850.1740	Whole Sediment: Acute Marine Invertebrates				Not required
N/A	Whole Sediment: Chronic Invertebrates Freshwater and Marine				Not required
850.3020	Honeybee Acute Contact Toxicity	44054902			See endnote ²⁴
Signature 			Name and Title Ann M. Tillman, Consultant		Date Feb. 24, 2015

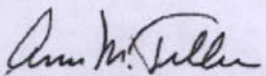
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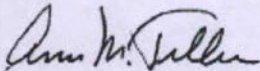
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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.3030	Honeybee Toxicity of Residues on Foliage				Not required
850.3040	Field Testing for Pollinators				Not required
870.6100	Delayed Neurotoxicity (Acute) – Hen				Not required
870.6200	Acute Neurotoxicity – Rat	43345405		OLD	See endnote ²⁵
870.3100	90-Day Oral: Rodent	43004601		OLD	See endnote ²⁶
870.3150	90-Day Oral: Non-Rodent	42932102		OLD	See endnote ²⁷
870.3200	21/28-Day Dermal Toxicity	44248301		OLD	See endnote ²⁸
870.3250	90-Day Dermal Toxicity				Not required
870.3465	90-Day Inhalation Toxicity	49253902			Not required
870.6100	28-Day Delayed Neurotoxicity Hen				Not required
870.6200	90-Day Neurotoxicity	44215701		OLD	See endnote ²⁹
870.4100	Chronic Oral Rodent	43345409		OLD	See endnote ³⁰
870.4200	Carcinogenicity	43345409		OLD	See endnote ³¹
		43345407		OLD	See endnote ³²
870.3700	Reproduction/Developmental Toxicity Screening Test	42932105		OLD	See endnote ³²
		42932106		OLD	See endnote ³²
Signature 			Name and Title Ann M. Tillman, Consultant		Date Feb. 24, 2015

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Date February 24, 2015		EPA Reg. No./File Symbol 88783-3		Page 7 of 25	
Applicant's/Registrant's Name & Address Summit Agro USA, LLC 8000 Regency Park, Suite 265 Cary, NC 27518		Product Technical Sulfentrazone			
Ingredient Sulfentrazone (CAS No. 122836-35-5)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.3800	2-Generation Reproduction: Rat	43345408 43869101		OLD OLD	See endnote ³³
870.6300	Developmental Neurotoxicity Study				Not required
870.5100	Bacterial Reverse Mutation Test	41911611		OLD	See endnote ³⁴
870.5300, 830.5375	In vitro Mammalian Cell Assay	43004604		OLD	See endnote ³⁵
870.5385, 870.5395, 870.5450	In vivo Cytogenetics	43004605 44248302		OLD OLD	See endnote ³⁶
870.7485	Metabolism and Pharmacokinetics	43345410		OLD	See endnote ³⁷
870.7200	Companion Animal Safety				Not required
870.7600	Dermal Penetration				Not required
870.7800	Immunotoxicity	48748601	FMC Corporation	PAY	See endnote ³⁸
875.1100	Dermal Exposure – Outdoor		Agricultural Handlers Exposure Task Force	PER	See endnote ³⁹
875.1200	Dermal Exposure - Indoor				Not required
875.1300	Inhalation Exposure – Outdoor		Agricultural Handlers Exposure Task Force	PER	See endnote ³⁹
Signature 			Name and Title Ann M. Tillman, Consultant		Date Feb 24, 2015

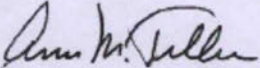
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Applicant's/Registrant's Name & Address		Product			
Summit Agro USA, LLC 8000 Regency Park, Suite 265 Cary, NC 27518		Technical Sulfentrazone			
Ingredient Sulfentrazone (CAS No. 122836-35-5)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
875.1500	Biological Monitoring		Agricultural Handlers Exposure Task Force	PER	See endnote ³⁹
875.1600	Data Reporting and Calculations		Agricultural Handlers Exposure Task Force	PER	See endnote ³⁹
875.1700	Product Use Information				Not required
875.2100	Dislodgeable Foliar Residue and Turf Transferable Residues	44802601 45005901 45005902 45005903 45005904 45005905 45005906 45005907 45005908 45005909 45005910 45005911 45138201 45138202	Agricultural Reentry Task Force Agricultural Reentry Task Force	OLD OLD OLD OLD OLD OLD OLD OLD OLD OLD OLD OLD PAY PAY	See endnote ³⁹
Signature			Name and Title		Date
			Ann M. Tillman, Consultant		Feb. 24, 2015

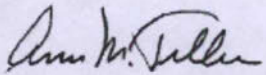
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Applicant's/Registrant's Name & Address Summit Agro USA, LLC 8000 Regency Park, Suite 265 Cary, NC 27518		Product Technical Sulfentrazone			
Ingredient Sulfentrazone (CAS No. 122836-35-5)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
875.2100	Dislodgeable Foliar Residue and Turf Transferable Residues (cont'd)	45175101	Agricultural Reentry Task Force	PAY	
		45175102	Agricultural Reentry Task Force	PAY	
		45175103	Agricultural Reentry Task Force	PAY	
		45175104	Agricultural Reentry Task Force	PAY	
		45175105	Agricultural Reentry Task Force	PAY	
		45191701	Agricultural Reentry Task Force	PAY	
		45224801	Agricultural Reentry Task Force	PAY	
		45344501	Agricultural Reentry Task Force	PAY	
		45432301	Agricultural Reentry Task Force	PAY	
		45432302	Agricultural Reentry Task Force	PAY	
		45432303	Agricultural Reentry Task Force	PAY	
		45469501	Agricultural Reentry Task Force	PAY	
		45469502	Agricultural Reentry Task Force	PAY	
		45480301	Agricultural Reentry Task Force	PAY	
		45480302	Agricultural Reentry Task Force	PAY	
		45491901	Agricultural Reentry Task Force	PAY	
		45491902	Agricultural Reentry Task Force	PAY	
		45491903	Agricultural Reentry Task Force	PAY	
45491904	Agricultural Reentry Task Force	PAY			
45491905	Agricultural Reentry Task Force	PAY			
Signature 			Name and Title Ann M. Tillman, Consultant		Date Feb. 24, 2015

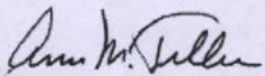
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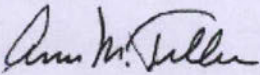
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Ingredient Sulfentrazone (CAS No. 122836-35-5)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
875.2100	Dislodgeable Foliar Residue and Turf Transferable Residues (cont'd)	45530101	Agricultural Reentry Task Force	PAY	
		45530102	Agricultural Reentry Task Force	PAY	
		45530103	Agricultural Reentry Task Force	PAY	
		45574001	Agricultural Reentry Task Force	PAY	
		45726301	Agricultural Reentry Task Force	PAY	
		45726302	Agricultural Reentry Task Force	PAY	
		46040301	Agricultural Reentry Task Force	PAY	
		46040302	Agricultural Reentry Task Force	PAY	
		46405901	Agricultural Reentry Task Force	PAY	
		46513901	Agricultural Reentry Task Force	PAY	
		46734001	Agricultural Reentry Task Force	PAY	
		46734002	Agricultural Reentry Task Force	PAY	
		46789301	Agricultural Reentry Task Force	PAY	
		46789302	Agricultural Reentry Task Force	PAY	
		48866801	Agricultural Reentry Task Force	PAY	
		49157401	Agricultural Reentry Task Force	PAY	
		49157402	Agricultural Reentry Task Force	PAY	
		49299201	Agricultural Reentry Task Force	PAY	
		49309201	Agricultural Reentry Task Force	PAY	
				44972201	
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Ingredient Sulfentrazone (CAS No. 122836-35-5)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
875.2100	Dislodgeable Foliar Residue and Turf Transferable Residues (cont'd)	44972202		OLD	
		44972203		OLD	
		44972204		OLD	
		44972205		OLD	
		44972206		OLD	
		44972207		OLD	
		44983501		OLD	
		45262901	Outdoor Residential Exposure TF	PAY	
		45262902	Outdoor Residential Exposure TF	PAY	
		45663701	Outdoor Residential Exposure TF	PAY	
		45663702	Outdoor Residential Exposure TF	PAY	
		45663703	Outdoor Residential Exposure TF	PAY	
		46042401	Outdoor Residential Exposure TF	PAY	
		46042402	Outdoor Residential Exposure TF	PAY	
46190501	Outdoor Residential Exposure TF	PAY			
875.2200	Soil Residue Dissipation				See 875.2100
875.2400	Dermal Exposure				See 875.2100
875.2500	Inhalation Exposure				See 875.2100
875.2600	Biological Monitoring				Not required
Signature 			Name and Title Ann M. Tillman, Consultant		Date Feb. 24, 2015

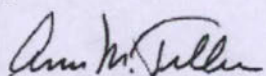
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Ingredient Sulfentrazone (CAS No. 122836-35-5)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
875.2700	Product Use Information				Not required
875.2800	Descriptions of Human Activity				Not required
875.2900	Data Reporting and Calculations				Not required
875.3000	Nondietary Ingestion Exposure				Not required
201-1	Droplet Size Spectrum	42565901 42608401 42907401 43254001 43485601 43485602 43485603 43485604 43493801 43493802 43508001 43535801 43535802 43657601		OLD OLD OLD OLD OLD OLD OLD OLD OLD OLD OLD OLD OLD OLD	
Signature 		Name and Title Ann M. Tillman, Consultant		Date Feb. 24, 2015	


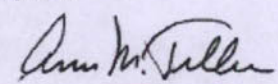
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Ingredient Sulfentrazone (CAS No. 122836-35-5)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
201-1	Droplet Size Spectrum (cont'd)	43657602		OLD	
		43665401		OLD	
		43665402		OLD	
		43757801		OLD	
		43757802		OLD	
		43766501		OLD	
		43766502		OLD	
		43766503		OLD	
		43766503		OLD	
		43766504		OLD	
		43781101		OLD	
		43803501		OLD	
		43832101		OLD	
		43832102		OLD	
		43845501		OLD	
		43845901		OLD	
		43925701		OLD	
		43953001		OLD	
		43953002		OLD	
		44010201		OLD	
Signature 		Name and Title Ann M. Tillman, Consultant		Date Feb. 24, 2015	

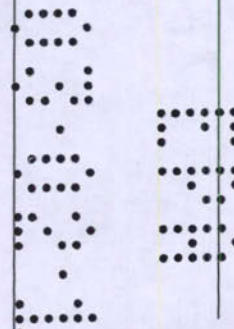
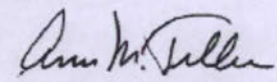
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Ingredient Sulfentrazone (CAS No. 122836-35-5)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
201-1	Droplet size spectrum (cont'd)	44070001		OLD	
		44100901		OLD	
		44134101		OLD	
		44178701		OLD	
		44310401		OLD	
		44640801		OLD	
		44640901		OLD	
		44641001		OLD	
		44696901		OLD	
		44747401		OLD	
		44763001		OLD	
		44878601		OLD	
		44908901		OLD	
202-1	Droplet Size Spectrum				See 201-1
850.4100	Tier 1: Seedling Emergence	43345411 43783601		OLD OLD	See endnote ⁴⁰
850.4150	Tier 1: Vegetative Vigor	43345412 43783602		OLD OLD	See endnote ⁴¹
Signature 			Name and Title Ann M. Tillman, Consultant		Date Feb. 24, 2015

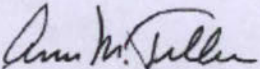
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Ingredient Sulfentrazone (CAS No. 122836-35-5)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.4400, 850.5400	Tier 1: Aquatic Plant Growth	43345413		OLD	See endnote ⁴²
		43651006		OLD	
		43651007		OLD	
		43651004		OLD	
		43651005		OLD	
850.4100	Tier 2: Seedling Emergence	43345411		OLD	See endnote ⁴³
		43783601		OLD	
850.4150	Tier 2: Vegetative Vigor	43345412		OLD	See endnote ⁴⁴
		43783602		OLD	
850.4400, 850.5400	Tier 2: Aquatic Plant Growth	43345413		OLD	See endnote ⁴⁵
		43651006		OLD	
		43651007		OLD	
		43651004		OLD	
		43651005		OLD	
850.4300	Terrestrial Field				Not required
850.4450	Aquatic Field				Not required
850.4025	Target Area Phytotoxicity				Not required
Signature 			Name and Title Ann M. Tillman, Consultant		Date Feb. 24, 2015

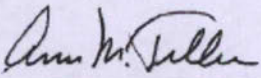
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Ingredient Sulfentrazone (CAS No. 122836-35-5)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
835.2120	Hydrolysis	41928202		OLD	See endnote ⁴⁶
835.2240	Photodegradation in Water	43588601		OLD	See endnote ⁴⁷
835.2410	Photodegradation in Soil	43345425		OLD	See endnote ⁴⁸
835.2370	Photodegradation in Air				Not required
835.4100	Aerobic Soil Metabolism	41928203 42932117		OLD OLD	See endnote ⁴⁹
835.4200	Anaerobic Soil Metabolism				Not required ⁵⁰
835.4300	Aerobic Aquatic Metabolism	43345426		OLD	See endnote ⁵¹
835.4400	Anaerobic Aquatic Metabolism			GAP	See endnote ⁵²
835.1230	Leaching/Adsorption/Desorption	43355903		OLD	See endnote ⁵³
835.1410	Volatility – Laboratory				Not required
835.8100	Volatility – Field				Not required
835.6100	Soil Field Dissipation Study	43345427 43651009 43651008 43345434		OLD OLD OLD OLD	
Signature 			Name and Title Ann M. Tillman, Consultant		Date Feb. 24, 2015

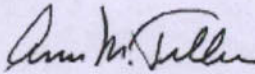
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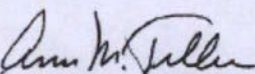
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Summit Agro USA, LLC 8000 Regency Park, Suite 265 Cary, NC 27518		Technical Sulfentrazone			
Ingredient Sulfentrazone (CAS No. 122836-35-5)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
835.6200	Aquatic Sediment Field Dissipation Study				Not required
835.6300	Forest Field Dissipation Study				Not required
835.6400	Combination and Tank Mixes				
835.7100	Ground Water Monitoring	46816001 47453601 47453602 43345434 43926814	FMC Corporation FMC Corporation FMC Corporation	PAY PAY PAY OLD OLD	See endnote ⁵⁴
850.6100	Environmental Chemistry Methods	48649401 48649402 48649403	FMC Corporation FMC Corporation FMC Corporation	PAY PAY PAY	
860.1300	Nature of the Residue: Plants	42932107 43656501 48397302 48397303 48397304	FMC Corporation FMC Corporation FMC Corporation	OLD OLD PAY PAY PAY	
Signature		Name and Title		Date	
		Ann M. Tillman, Consultant		Feb. 24, 2015	

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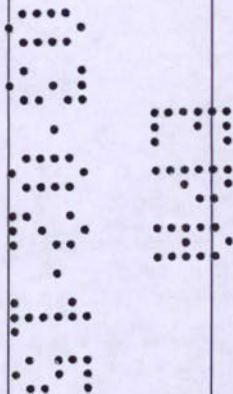
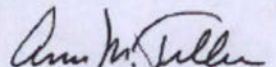
Date February 24, 2015		EPA Reg. No./File Symbol 88783-3		Page 18 of 25	
Applicant's/Registrant's Name & Address Summit Agro USA, LLC 8000 Regency Park, Suite 265 Cary, NC 27518		Product Technical Sulfentrazone			
Ingredient Sulfentrazone (CAS No. 122836-35-5)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1300	Nature of the Residue: Livestock	43345414 43345415		OLD OLD	
860.1850	Confined Rotational Crops	43761702 43345428 44450201		OLD OLD OLD	
Signature 			Name and Title Ann M. Tillman, Consultant		Date Feb. 24, 2015

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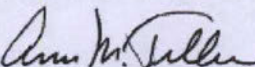
Date February 24, 2015		EPA Reg. No./File Symbol 88783-3		Page 9 of 25	
Applicant's/Registrant's Name & Address Summit Agro USA, LLC 8000 Regency Park, Suite 265 Cary, NC 27518		Product Technical Sulfentrazone			
Ingredient Sulfentrazone (CAS No. 122836-35-5)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1340	Residue Analytical Methods	44450202		OLD	
		42932111		OLD	
		42932110		OLD	
		42932109		OLD	
		42932108		OLD	
		43278201		OLD	
		43651015		OLD	
		43651014		OLD	
		43761703		OLD	
		43761704		OLD	
		43761705		OLD	
		43926813		OLD	
		43926806		OLD	
		43953801		OLD	
		44005602		OLD	
		44005601		OLD	
		44118802		OLD	
		44118801		OLD	
		44450202		OLD	
Signature 		Name and Title Ann M. Tillman, Consultant		Date Feb. 24, 2015	

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Applicant's/Registrant's Name & Address Summit Agro USA, LLC 8000 Regency Park, Suite 265 Cary, NC 27518		Product Technical Sulfentrazone			
Ingredient Sulfentrazone (CAS No. 122836-35-5)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1360	Multiresidue Method	43345417		OLD	
		43345416		OLD	
		43651013		OLD	
860.1380	Storage Stability	42932112	FMC Corporation	OLD	
		42932113		OLD	
		43345418		OLD	
		43345419		OLD	
		43345420		OLD	
		43345421		OLD	
		43761706		OLD	
		43926812		OLD	
		43926811		OLD	
45487902	PAY				
860.1500	Magnitude of the Residue in Plants: Asparagus	45752601	IR-4	PUBLIC	
860.1500	Magnitude of the Residue in Plants: Berry (group 13-07)	48397309	FMC Corporation	PAY	
Signature 		Name and Title Ann M. Tillman, Consultant		Date Feb. 24, 2015	

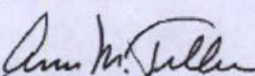
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Summit Agro USA, LLC 8000 Regency Park, Suite 265 Cary, NC 27518		Technical Sulfentrazone			
Ingredient Sulfentrazone (CAS No. 122836-35-5)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1500	Magnitude of the Residue in Plants: Brassica Vegetables	47311401 47311402 45393501	IR-4 IR-4 IR-4	PUBLIC PUBLIC PUBLIC	
860.1500	Magnitude of the Residue in Plants: Citrus	48397308	FMC Corporation	PAY	
860.1500	Magnitude of the Residue in Plants: Corn	45567402	FMC Corporation	PAY	
860.1500	Magnitude of the Residue in Plants: Flax	47311407	IR-4	PUBLIC	
860.1500	Magnitude of the Residue in Plants: Horseradish	45393502	IR-4	PUBLIC	
860.1500	Magnitude of the Residue in Plants: Melon	47311403	IR-4	PUBLIC	
860.1500	Magnitude of the Residue in Plants: Mint	45393503	IR-4	PUBLIC	
860.1500	Magnitude of the Residue in Plants: Vegetable, corn and tuberous subgroup 1C	45582201	IR-4	PUBLIC	
860.1500	Magnitude of the Residue in Plants: Fruiting Vegetable	47311404 47311405	IR-4 IR-4	PUBLIC PUBLIC	
860.1500	Magnitude of the Residue in Plants: Peanuts	45077902	FMC Corporation	PAY	
860.1500	Magnitude of the Residue in Plants: Peas and Beans	45567404 47311406	FMC Corporation IR-4	PAY PUBLIC	
Signature			Name and Title		Date
			Ann M. Tillman, Consultant		Feb. 24, 2015

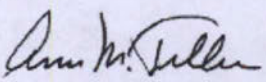
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Applicant's/Registrant's Name & Address Summit Agro USA, LLC 8000 Regency Park, Suite 265 Cary, NC 27518			Product Technical Sulfentrazone		
Ingredient Sulfentrazone (CAS No. 122836-35-5)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1500	Magnitude of the Residue in Plants: Pistachio	48397306	FMC Corporation	PAY	
860.1500	Magnitude of the Residue in Plants: Rhubarb	48514802	IR-4	PUBLIC	
860.1500	Magnitude of the Residue in Plants: Soybeans	42932114 42932115 43278202 43345422 43345423 44118803		OLD OLD OLD OLD OLD OLD	
860.1500	Magnitude of the Residue in Plants: Wheat	48514803	IR-4	PUBLIC	
860.1500	Magnitude of the Residue in Plants: Strawberry	47311408	IR-4	PUBLIC	
860.1500	Magnitude of the Residue in Plants: Sugarcane	45077904	FMC Corporation	PAY	
860.1500	Magnitude of the Residue in Plants: Sunflower (Subgroup 20B)	45096501	IR-4	PUBLIC	
860.1500	Magnitude of the Residue in Plants: Tobacco	44248401 44248402 44248403		OLD OLD OLD	
860.1500	Magnitude of the Residue in Plants: Tree Nuts	48397306	FMC Corporation	PAY	
Signature 			Name and Title Ann M. Tillman, Consultant		Date Feb. 24, 2015

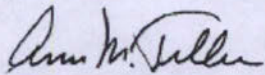
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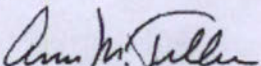
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Applicant's/Registrant's Name & Address Summit Agro USA, LLC 8000 Regency Park, Suite 265 Cary, NC 27518			Product Technical Sulfentrazone		
Ingredient Sulfentrazone (CAS No. 122836-35-5)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1500	Magnitude of the Residue in Plants: Turnip	48514801	IR-4	PUBLIC	
860.1520	Magnitude of the Residue in Processed Food or Feed: Citrus	48397308	FMC Corporation	PAY	
860.1520	Magnitude of the Residue in Processed Food or Feed: Corn	45567403	FMC Corporation	PAY	
860.1520	Magnitude of the Residue in Processed Food or Feed: Flax	47311407	IR-4	PUBLIC	
860.1520	Magnitude of the Residue in Processed Food or Feed: Mint	45393503	IR-4	PUBLIC	
860.1520	Magnitude of the Residue in Processed Food or Feed: Vegetable, corm and tuberous subgroup 1C	45582201	IR-4	PUBLIC	
860.1520	Magnitude of the Residue in Processed Food or Feed: Fruiting Vegetable	47311404	IR-4	PUBLIC	
860.1520	Magnitude of the Residue in Processed Food or Feed: Peanuts	45077903	FMC Corporation	PAY	
860.1520	Magnitude of the Residue in Processed Food or Feed: Soybeans	42932116 43278202		OLD OLD	
Signature 			Name and Title Ann M. Tillman, Consultant		Date Feb. 24, 2015

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Applicant's/Registrant's Name & Address		Product			
Summit Agro USA, LLC 8000 Regency Park, Suite 265 Cary, NC 27518		Technical Sulfentrazone			
Ingredient Sulfentrazone (CAS No. 122836-35-5)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1520	Magnitude of the Residue in Processed Food or Feed: Wheat	48514803	IR-4	PUBLIC	
860.1520	Magnitude of the Residue in Processed Food or Feed: Sugarcane	45077905	FMC Corporation	PAY	
860.1520	Magnitude of the Residue in Processed Food or Feed: Sunflower (Group 20B)	45096501	IR-4	PUBLIC	
860.1480	Magnitude of the Residue in Meat, Milk, Poultry, and Eggs				Not required
860.1400	Nature and Magnitude of the Residue in Potable Water				Not required
860.1400	Magnitude of the Residue in Fish				Not required
860.1400	Magnitude of the Residue in Plants Resulting from the Use of Irrigation Water				Not required
860.1460	Magnitude of the Residue in Food Handling Establishments				Not required
Signature			Name and Title		Date
			Ann M. Tillman, Consultant		Feb. 24, 2015

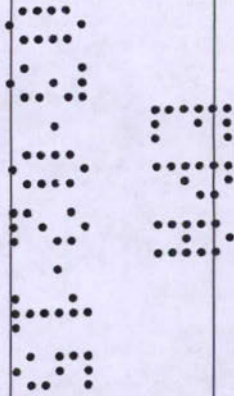
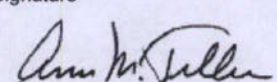
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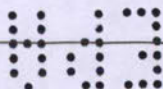
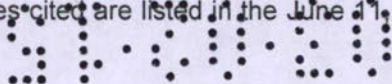
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Applicant's/Registrant's Name & Address Summit Agro USA, LLC 8000 Regency Park, Suite 265 Cary, NC 27518		Product Technical Sulfentrazone			
Ingredient Sulfentrazone (CAS No. 122836-35-5)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1900	Field Rotational Crops	43926803		OLD	
		43926804		OLD	
		43926805		OLD	
		43926807		OLD	
		43926808		OLD	
		43926809		OLD	
		43926810		OLD	
		44450203		OLD	
		44450205		OLD	
		44450206		OLD	
		44118807		OLD	
		44118806		OLD	
		43651012		OLD	
		44118805		OLD	
		43345431		OLD	
		44118804		OLD	
		43651010		OLD	
		44450204		OLD	
Signature 		Name and Title Ann M. Tillman, Consultant		Date Feb. 24, 2015	

Endnotes for Data Matrix for Technical Sulfentrazone

- ¹ **830.1650** - These data are not required for the registration of a manufacturing use product. See 830.1620 for production process information.
- ² **830.6315** - Summit Agro USA, LLC requests a waiver from this data requirement because Technical Sulfentrazone is a solid and is not expected to be flammable.
- ³ **830.6316** - Summit Agro USA, LLC requests a waiver from this data requirement because sulfentrazone does not have the chemical bonds or functional groups associated with explosive chemicals.
- ⁴ **830.6319** - This data requirement is required when the MUP is an emulsifiable liquid and to be diluted with petroleum solvents. Technical Sulfentrazone is a technical material that is a solid and is not to be diluted with petroleum solvents. This data requirement is not applicable to Technical Sulfentrazone.
- ⁵ **830.6321** - These data are not required unless the product is an end-use product. Technical Sulfentrazone is a technical grade material and this data requirement is not applicable.
- ⁶ **830.7100** - This requirement is not applicable to Technical Sulfentrazone because it is a solid.
- ⁷ **830.7220** - This requirement is not applicable to Technical Sulfentrazone because it is a solid. The melting point of Technical Sulfentrazone was determined and that data is presented in MRID 48890704.
- ⁸ **830.7520** - A waiver was submitted by Summit Agro USA, LLC for this data requirement for Technical Sulfentrazone because it is not a fibrous material and is not a water-insoluble material.
- ⁹ **870.1100** - The study cited is listed in the June 5, 2014 Preliminary Human Health Risk Assessment for Registration Review (Human Health Risk Assessment, DP Barcode D410365) as satisfying the data requirement. Note MRID 41911606 was also listed under 870.1200, but this appears to be an acute oral study. As such, MRID 41911606 is also cited under 870.1100.
- ¹⁰ **870.1200** - MRID numbers 41911606 and 42286400 were listed in the Human Health Risk Assessment as satisfying this data requirement. However, MRID number 41911606 appears to correspond to an acute oral study (see 870.1100) and 42286400 appears to be a transmittal document for a response for a dermal sensitization study. Because neither of these citations correspond to an acute dermal study, MRID number 41911607 is cited.
- ¹¹ **870.1300** - The study cited is listed in the June 5, 2014 Human Health Risk Assessment as satisfying the data requirement.
- ¹² **870.2400** - The study cited is listed in the June 5, 2014 Human Health Risk Assessment as satisfying the data requirement.
- ¹³ **870.2500** - The study cited is listed in the June 5, 2014 Human Health Risk Assessment as satisfying the data requirement.
- ¹⁴ **870.2600** - The study cited is listed in the June 5, 2014 Human Health Risk Assessment as satisfying the data requirement.
- ¹⁵ **850.2100** - The study cited is listed in the June 11, 2014 Preliminary Ecological Risk Assessment for Registration Review (Ecological Risk Assessment, DP Barcode D409753) as satisfying the data requirement.
- ¹⁶ **850.2200** - The studies cited are listed in the June 11, 2014 Ecological Risk Assessment as satisfying the data requirement.
- ¹⁷ **850.2300** - The studies cited are listed in the June 11, 2014 Ecological Risk Assessment as satisfying the data requirement.
- ¹⁸ **850.1075** - The studies cited are listed in the June 11, 2014 Ecological Risk Assessment as satisfying the data requirement.



Endnotes for Data Matrix for Technical Sulfentrazone

- ¹⁹ **850.1010** – The study cited is listed in the June 11, 2014 Ecological Risk Assessment as satisfying the data requirement.
- ²⁰ **850.1025, 850.1035, 850.1045, 850.1055, 850.1075** – The studies cited are listed in the June 11, 2014 Ecological Risk Assessment as satisfying the data requirement.
- ²¹ **850.1300** – The study cited is listed in the June 11, 2014 Ecological Risk Assessment as satisfying the data requirement.
- ²² **850.1400** – The study cited is listed in the June 11, 2014 Ecological Risk Assessment as satisfying the data requirement.
- ²³ **850.1710, 850.1730, 850.1850** – Although based on the Koc, these data are not typically required, MRID 43345433 is cited. This study was identified as acceptable in the June 11, 2014 Ecological Risk Assessment.
- ²⁴ **850.3020** – The study cited is listed in the June 11, 2014 Ecological Risk Assessment as satisfying the data requirement. MRID number 43678166 is also listed in the Ecological Risk Assessment, but this study appears to correspond to an azoxystrobin study submitted by Syngenta, not a sulfentrazone study. As such, MRID 43678166 is not cited.
- ²⁵ **870.6200** – The study cited is listed in the June 5, 2014 Human Health Risk Assessment as satisfying the data requirement.
- ²⁶ **870.3100** – The study cited is listed in the June 5, 2014 Human Health Risk Assessment as satisfying the data requirement.
- ²⁷ **870.3150** – The study cited is listed in the June 5, 2014 Human Health Risk Assessment as satisfying the data requirement.
- ²⁸ **870.3200** – The study cited is listed in the June 5, 2014 Human Health Risk Assessment as satisfying the data requirement.
- ²⁹ **870.6200** – MRID 43345405 is listed in the June 5, 2014 Human Health Risk Assessment as satisfying the data requirement. However, this citation corresponds to an acute neurotoxicity study. Therefore, MRID 44215701, a subchronic neurotoxicity study with sulfentrazone is cited.
- ³⁰ **870.4100** – The study cited is listed in the June 5, 2014 Human Health Risk Assessment as satisfying the data requirement.
- ³¹ **870.4200** – The studies cited are listed in the June 5, 2014 Human Health Risk Assessment as satisfying the data requirement.
- ³² **870.3700** – The studies cited are listed in the June 5, 2014 Human Health Risk Assessment as satisfying the data requirement.
- ³³ **870.3800** – The studies cited are listed in the June 5, 2014 Human Health Risk Assessment as satisfying the data requirement.
- ³⁴ **870.5100** – The study cited is listed in the June 5, 2014 Human Health Risk Assessment as satisfying the data requirement.
- ³⁵ **870.5300, 830.5375** – The study cited is listed in the June 5, 2014 Human Health Risk Assessment as satisfying the data requirement.
- ³⁶ **870.5385, 830.5395, 870.5450** – The studies cited are listed in the June 5, 2014 Human Health Risk Assessment as satisfying the data requirement.
- ³⁷ **870.7485** – The study cited is listed in the June 5, 2014 Human Health Risk Assessment as satisfying the data requirement.
- ³⁸ **870.7800** – The study cited is listed in the June 5, 2014 Human Health Risk Assessment as satisfying the data requirement.

Endnotes for Data Matrix for Technical Sulfentrazone

- ³⁹ **875.1100, 875.1300, 875.1500, 875.1600** – Summit Agro USA, LLC is a "Participating Company" in good standing with the Agricultural Handlers Exposure Task Force (AHETF). Data submitted by the AHETF satisfy this data requirement. A letter of authorization for reliance on AHETF data can be provided upon request.
- ⁴⁰ **850.4100** – The study cited is listed in the June 11, 2014 Ecological Risk Assessment as satisfying the data requirement. Note: MRID 43783601, supplement to 43345411, is also cited.
- ⁴¹ **850.4150** – The study cited is listed in the June 11, 2014 Ecological Risk Assessment as satisfying the data requirement. Note: MRID 43783602, supplement to 43345412, is also cited.
- ⁴² **850.4400, 850.5400** – The studies cited are listed in the June 11, 2014 Ecological Risk Assessment as satisfying the data requirement. Note: although MRID 43651006 was classified as supplemental, EPA did not require this study to be replaced and relied on it for registration review purposes.
- ⁴³ **850.4100** – The study cited is listed in the June 11, 2014 Ecological Risk Assessment as satisfying the data requirement. Note: MRID 43783601, supplement to 43345411, is also cited.
- ⁴⁴ **850.4150** – The study cited is listed in the June 11, 2014 Ecological Risk Assessment as satisfying the data requirement. Note: MRID 43783602, supplement to 43345412, is also cited.
- ⁴⁵ **850.4400, 850.5400** – The studies cited are listed in the June 11, 2014 Ecological Risk Assessment as satisfying the data requirement. Note: although MRID 43651006 was classified as supplemental, EPA did not require this study to be replaced and relied on it for registration review purposes.
- ⁴⁶ **835.2120** – The study cited is listed in the Sept. 9, 2009 EFED Problem Formulation for Registration Review (Problem Formulation) as satisfying the data requirement.
- ⁴⁷ **835.2240** – The study cited is listed in the Sept. 9, 2009 Problem Formulation as satisfying the data requirement.
- ⁴⁸ **835.2410** – The study cited is listed in the Sept. 9, 2009 Problem Formulation as satisfying the data requirement.
- ⁴⁹ **835.4100** – The studies cited are listed in the Sept. 9, 2009 Problem Formulation as satisfying the data requirement. Note: it appears MRID 41922803 was listed in error and that the correct MRID should be 41928203 and is cited herein.
- ⁵⁰ **835.4200** – The study submitted was not considered acceptable in the June 11, 2014 Ecological Risk Assessment, but EPA notes that this is "not a required study" (page 31). Therefore, no data are cited here.
- ⁵¹ **835.4300** – The study cited is listed in the Sept. 9, 2009 Problem Formulation as satisfying the data requirement.
- ⁵² **835.4400** – The study submitted was not considered acceptable in the June 11, 2014 Ecological Risk Assessment and EPA requested the submission of additional data to satisfy the data requirement. Therefore, this data requirement is identified as "data gap."
- ⁵³ **835.1230** – The study cited is listed in the Sept. 9, 2009 Problem Formulation as satisfying the data requirement.
- ⁵⁴ **835.7100** – The studies cited were listed in the June 11, 2014 Ecological Risk Assessment.

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